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(TPSAC)

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P R O C E E D I N G S

(9:00 a.m.)

Call to Order

DR. SAMET: Good morning. This is Jonathan Samet speaking here at the TPSAC. It is 9:00 a.m. in Maryland. It's 6:00 a.m. here in California. Good morning to you all, and thanks for joining. I have two statements to make, and then we'll introduce the committee.

For topics such as those being discussed at today's meeting, there are often a variety of opinions, some of which are quite strongly held. Our goal is that today's meeting will be a fair and open forum for discussion of these issues, and that individuals can express their views without interruption. Thus, as a gentle reminder, individuals will be allowed to speak into the record only if recognized by the chair. We look forward to a productive meeting.

In the spirit of the Federal Advisory Committee Act and the Government in the Sunshine Act, we ask that the Advisory Committee members take care that their conversations about the topic

at hand take place in the open forum of the meeting. We are aware that members of the media are anxious to speak with the FDA about these proceedings. However, FDA will refrain from discussing the details of this meeting with the media until its conclusion. Also, the committee is reminded to -- well, perhaps less applicable today -- reminded to please refrain from discussing the details of the meeting during breaks or lunch. Thank you.

I guess we have the new technology, and we'll see how this goes today. And we've had excellent instructions by Tom Graham.

Karen?

Conflict of Interest Statement

DR. TEMPLETON-SOMERS: Hi. I'm Karen Templeton-Somers, not Cristi Stark. Cristi could not make it today.

Good morning. I'd like to remind everyone to please silence your cell phones if you have not done so already. I would also like to identify the FDA press contact, Tesfa Alexander.

Could you please stand up?

Also, for our online participants, a few reminders. If you could please mute your phone when you are not speaking; and when you do speak, please state your name into the record so that we can make sure that we all know who is talking.

The Food and Drug Administration is convening today's meeting of the Menthol Report Subcommittee of the Tobacco Products Scientific Advisory Committee under the authority of the Federal Advisory Committee Act of 1972. With the exception of the industry representatives, all members are special government employees, and are subject to federal conflict of interest laws and regulations.

The following information on the status of the subcommittee's compliance with federal ethics and conflict of interest laws covered by, but not limited to, those found at 18 USC Section 208 and Section 712 of the Federal Food, Drug and Cosmetic Act is being provided to participants in today's meeting and to the public.

FDA has determined that the members of this subcommittee are in compliance with the federal ethics and conflict of interest laws. Under 18 USC Section 208, Congress has authorized FDA to grant waivers to special government employees and regular federal government employees who have potential conflicts of interest when it is determined that the agency's need for a particular individual's services outweighs his or her potential financial conflict of interest.

Under Section 712 of the FD&C Act, Congress has authorized FDA to grant waivers to special government employees and regular federal employees with potential financial conflicts when necessary to afford the committee essential expertise.

Related to the discussions of today's meeting, members of this committee have been screened for potential financial conflicts of interest of their own, as well as those imputed to them, including those of their spouses or minor children, and, for the purposes of 18 USC Section

208, their employers. These interests may include investments, consulting, expert witness testimony, contracts, grants, CRADAs, teaching, speaking, writing, patents, royalties, and primary employment.

Today's agenda involves receiving a presentation and discussing the timelines and structure of the Tobacco Products Scientific Advisory Committee's required report to the Secretary of Health and Human Services regarding the impact of the use of menthol in cigarettes on the public health.

This is a particular matters meeting, during which general issues will be discussed. Based on the agenda for today's meeting and all financial interests reported by the subcommittee members, no conflict of interest waivers have been issued in connection with this meeting.

To ensure transparency, we encourage all standing committee members and consultants to disclose any public statements that they have made concerning the issues before the committee.

With respect to FDA's invited industry representatives, we would like to disclose that Drs. Daniel Heck and John Lauterbach and Mr. Arnold Hamm are participating in this meeting as nonvoting industry representatives, acting on behalf of the interests of the tobacco manufacturing industry, the small business tobacco manufacturing industry, and tobacco growers, respectively. Their role at this meeting is to represent these industries in general and not any particular company. Dr. Heck is employed by Lorillard Tobacco Company, Dr. Lauterbach is employed by Lauterbach & Associates, LLC, and Mr. Hamm is retired.

FDA encourages all other participants to advise the committee of any financial relationships that they may have with any firms at issue. Thank you.

For the audience here in the room, if you check your roster in your agenda packet there, you can see the list of people who are attending by telephone and Adobe today by noting that there's a

star in front of their name. Thank you.

Introduction of Committee Members

Okay. We need to introduce the committee members.

Dr. Lauterbach, being here in the room, would you like to go first?

DR. LAUTERBACH: I'm John Lauterbach, Lauterbach & Associates, LLC, Macon, Georgia. We're consultants in tobacco chemistry and toxicology. And not only representing good science, I do represent the interests of the small business tobacco manufacturers.

DR. TEMPLETON-SOMERS: Dr. Samet? Dr. Samet, did we lose you?

DR. SAMET: Sorry, Karen. I had the mute on.

Jon Samet, chair of TPSAC, from the University of Southern California.

Are you going to continue to call people around or do you want me to go ahead and do that?

DR. TEMPLETON-SOMERS: You can do it if you'd like.

DR. SAMET: Let's see. So let's start with Mr. Hamm.

MR. HAMM: Yes. I'm Arnold Hamm. I'm representing the U.S. tobacco growers.

DR. SAMET: Greg? Greg Connolly?

DR. CONNOLLY: Greg Connolly from the Harvard School of Public Health.

DR. SAMET: Dan?

DR. HECK: Dan Heck from the Lorillard Tobacco Company, representing the tobacco manufacturers.

DR. SAMET: Dorothy?

DR. HATSUKAMI: Dorothy Hatsukami from the University of Minnesota.

DR. SAMET: Karen?

MS. DELEEUW: Karen DeLeeuw, Colorado Department of Public Health and Environment, and I am representing government.

DR. SAMET: Mark?

DR. CLANTON: Mark Clanton. I work for the American Cancer Society, and I'm providing input for pediatrics, public health, and oncology.

DR. SAMET: Neal? Neal Benowitz?

[No response.]

DR. SAMET: Okay. Patricia?

DR. HENDERSON: Yes. Good morning. Patricia Nez Henderson, and I'm with the Black Hills Center for American Indian Health.

DR. SAMET: Great. And, let's see, Neal Benowitz, are you on?

DR. BENOWITZ: I am Neal Benowitz, University of California San Francisco.

DR. SAMET: Great. I think we'll move on now to the charge to the committee.

Corinne?

DR. TEMPLETON-SOMERS: Thank you. I would also like to ask that the people on the intercom, I think that you may need to use your regular handset instead of speakerphone. We appear to be picking up extra noise when it's on speakerphone. And please mute when you're not speaking. Thank you.

Charge to the Committee

DR. HUSTEN: Good morning. This is the

first meeting of the Menthol Report Subcommittee, and I'm going to talk a little bit about the roles of the subcommittee versus the roles of the TPSAC.

Just a reminder, the questions to be addressed in the menthol report are, what are the impact of menthol cigarettes on public health, including such use among children, African Americans, Hispanics, and other racial and ethnic minorities; and, what recommendations, if any, does TPSAC have for FDA regarding menthol cigarettes?

Again, a reminder that in its review and consideration of recommendations, the TPSAC shall address the risk and benefits to the population as a whole, including users and non-users of tobacco products; the increased or decreased likelihood that existing users of tobacco products will stop using such products; the increased or decreased likelihood that those who do not use tobacco products will start using such products; technical achievability; and the potential for effects on adolescent and adult users and non-tobacco users,

and the creation of significant demand for contraband.

The role of the subcommittee is to determine the structure of the menthol report, including chapter topics and the structure of the chapters; to write the menthol report, describing the evidence regarding the impact of menthol cigarettes on public health, and draw conclusions about the strength of the evidence on each topic of interest. And the work of the subcommittee will be referred back to the full TPSAC for discussion and deliberation.

The role of the TPSAC is to discuss and deliberate on evidence that will be presented to the committee in the various meetings; to discuss and deliberate on the work produced by the subcommittee; and to develop the recommendations that will be included in the report.

The report, as a reminder, is due March 23rd of 2011. The TPSAC has requested information, and that information will be presented to the TPSAC as it becomes available

over the next five months. But that means that the workgroups will need to review and incorporate that information as it becomes available. We expect that referral of the draft report to the full TPSAC will need to occur around February 2011.

Now, Dr. Somers is going to talk a little bit about the logistics because I think that will answer some of the specific questions that folks may have about the report. And then we'll take clarifying questions after her presentation.

Menthol Report Writing Process

DR. TEMPLETON-SOMERS: Hi. I'm Karen Templeton-Somers, and I'm the leader of the group within the Center for Tobacco Products that works with the TPSAC, and I'll be talking about some of the logistical considerations necessary for the process of writing the menthol report.

The Menthol Report Subcommittee of the TPSAC was established specifically for the purpose of writing the required report on the issue of the impact of the use of menthol in cigarettes on the

public health. Participation in the Menthol Report Subcommittee was offered to all of the voting TPSAC members, as well as all three of the nonvoting industry representatives. As you can see from the subcommittee roster in your agenda packet, most of them believed that they had the time and ability to participate.

In the interest of holding as much of the process as practical in open session, this subcommittee will be holding at least two open meetings. These meetings will comply with the FACA rules that would apply to the parent committee. They'll be announced in the Federal Register. They'll be open to the public. They will include an open public hearing and a mechanism for the public to provide written comments.

Today is the first of these meetings, and it's expected to be largely an organizational meeting. Dr. Samet, who will also be chairing the subcommittee, will be sharing his view of the overall structure of the report for discussion,

and we will also be working on the timelines and provide rules of the road for the writing process.

Here's the general plan for writing the menthol report. First of all, FDA will not be writing any portion of the report. The report will be written by the Menthol Report Subcommittee members.

Once the chapters of the report have been decided, workgroups of two to three subcommittee members will collaborate to write the drafts. The workgroups will not write in open session. They will be able to work independently or meet either in person or electronically. Any time two or more SGEs are meeting, communicating, or exchanging drafts, they need to include the DFO in the process.

Some of the information available for review and consideration will be trade secret or confidential commercial information. This thus requires that the workgroups do not work in open session, and it also means that the workgroups cannot include participants who are not special

government employees.

It may be that once the structure of the report is finalized and the workgroups start getting into the process, they'll find that they need to bring in additional people with different expertise that's not already represented. Those extra people who are already appointed special government employees will be able to participate after they are cleared for conflict of interest. Work groups can only confer and consult within the group. They cannot ask for input from colleagues or from students.

We do have a professional science writer who will be available to the subcommittee workgroups to provide technical assistance in preparing the drafts of the report. This is an administrative position, and the science writer will not be deliberating or contributing to the scientific analysis, but helping with the actual putting of things on paper, formatting, getting the footnotes together, et cetera.

We do have some ground rules in order to

accomplish this. The SGEs on the subcommittee will be required to respond to regular conflict of interest screening throughout the writing process. We need to keep it updated. We need to keep it correct.

The drafts in progress must be kept confidential. They cannot be shared with anyone outside the workgroup other than the chair, Dr. Samet, the science writer, and the DFO or designee. We're realizing that the DFO/designee may have quite a few of these little workgroups to participate in, so she may be designating somebody else to stand in occasionally.

The DFO's role will be purely administrative and not to be part of the scientific discussion. The DFO will maintain records of all drafts in progress and will set up and administer any workgroup telecons or meetings.

In the writing of the report, the subcommittee will be relying on the materials presented at TPSAC meetings in preparing the report. The TPSAC meeting materials include the

background materials, public submissions, presentations, and the deliberations and discussions from the TPSAC meetings. The subcommittee participants will also be able to draw on their own expertise when analyzing the scientific information and preparing their report.

It may come up during the course of the writing that there's information that a workgroup member would like to include in the report, but that information has not been presented to TPSAC. If that's the case, they need to provide the information to the DFO. The DFO will see that the FDA reviews the new information and, as appropriate and after being reviewed for the need for reduction, included as part of an upcoming TPSAC meeting. Once the information has been presented to TPSAC, it's eligible for inclusion in the report.

The fact that the workgroups will be reviewing trade secret and commercial confidential information means that the industry representatives will not be participating in the

writing workgroups. However, CTP values the unique experience and viewpoint of the industry representatives, and actively sought for a mechanism to include them in the process of preparing this menthol report, given the restrictions on access to trade secret and commercial confidential information.

There are two ways in which the industry representatives can participate. The subcommittee will have at least two open meetings in which the industry representatives can participate. They will also be able to participate in the full TPSAC meetings where the report and recommendations are discussed by the TPSAC. And for a number of our TPSAC meetings between now and March, there will be updates from the Menthol Subcommittee. In addition, we would like to ask the industry reps to collaborate on a document that would serve as an industry perspective.

We're not just going to hand this over and twiddle our thumbs in the meantime. We realize that you have a huge task ahead of you,

and CTP would like to support the subcommittee in this process as much as we possibly can.

So we'll be continuing to obtain the information that was requested at earlier TPSAC meetings, starting at the very first meeting. The DFO will provide administrative support to the workgroups, assisting them in scheduling meetings and telecons and by maintaining records of all the drafts. And if there's anything else that you need, please let us know and we'll see what we can do.

Given the odd format of this meeting, I think maybe Corinne and I will both go back to our seats to take the questions, if that's okay. Thank you.

Clarifying Questions

DR. SAMET: So this is the opportunity for the committee to ask clarifying questions. I think some of this may perhaps become clear as we also move forward in our subcommittee discussions. But I think if there are clarifying questions to the general description of the process that you

just heard from Corinne and Karen, please raise your hand.

I notice that, Arnold, you have your hand up, so go ahead with your question, please.

MR. HAMM: Thank you, Dr. Samet. A question for Karen or Corinne.

I noted that CTP has asked the industry reps to write an industry perspective. What are the guidelines of that? Are they similar to the guidelines for writing the subcommittee report?

DR. HUSTEN: If there are any particular directions that Dr. Samet gives for other sections, those would apply to this document as well. But, otherwise, the industry is free to include whatever information they would like to.

DR. TEMPLETON-SOMERS: You are free from a lot of the restrictions of the rest of the committee. You don't have to involve the DFO in the process, or the science writer, and you are not held to the confidentiality restrictions.

MR. HAMM: Thank you.

DR. SAMET: Let's see. Dan?

DR. HECK: Yes. The confidential trade secret information that was referred to, who makes the call as to what comprises confidential trade secret information? Is that the owner of the information?

DR. TEMPLETON-SOMERS: It's a process. All if the information, for example, which was submitted in response to the 904(b) request, before it's released would have to be reviewed by our information availability staff. I'm not sure of any disclosure. And then, if it is from a particular company, then there is a process that's gone through in order to see if they agree that it's releasable. It's a time-consuming process.

DR. HUSTEN: I'm sorry. So industry can identify information, but we also independently need to look at it with our disclosure experts to make sure there isn't other information that would be commercial confidential or trade secret, even if the industry hadn't identified it as such.

DR. HECK: Just as a follow-up, then FDA's declaration of confidential trade secret

would trump that of the actual owner of the information who may have submitted it?

DR. TEMPLETON-SOMERS: I think it's a process. I mean, we review it first because if it's going to be on our website, we have to be secure that it's releasable. But, in general, when it comes up, it's reviewed and then it's discussed. So it's back and forth, and it's a mutual agreement.

DR. SAMET: Greg Connolly?

DR. CONNOLLY: Just a couple points. One, I think the PowerPoints did cover this. I think it would be good to just reference the statute and the law up front whenever we reference our mission and task, the section of the law and the section under menthol cigarettes. And then -- I think you've done that -- define public health just for grounding what we do, so anything we do is grounded in statutes.

Number two, will there be confidentiality agreements that members will have to sign before they look at a document that would be deemed to be

confidential?

DR. HUSTEN: Well, as you know --

DR. CONNOLLY: Let me just raise the questions, then you can answer. Three, is there a possibility for a movement of the date of the report? I notice that there was a movement of the date for reporting of the tobacco industry. This is a large, large task. Any consideration to the date?

Number three, on evidence, I didn't see what CTP would be contributing to the committee for evidence. I understand CTP would be issuing the report, but should we look upon CTP to answer questions and to assign staff to discover evidence, if evidence exists, or bring evidence before the committee relative to matters concerning menthol? Just so that we get a complete, clear understanding of what science is available.

So those are my three questions -- confidentiality; is there a possibility of moving the date of the final report, which you have

already done for the tobacco industry reporting; then, number three, what role will CTP play in producing evidence for the committee as they develop the report.

DR. HUSTEN: Let me answer those, and if I miss something, let me know.

The confidential information will be identified for you so that we know which information is considered confidential commercial information or trade secret.

The date is set in statute, and so it will not be able to be changed. We understand that means a tight timeline. We understand that means you may not have everything that you might want to have in order to write the report. But it is set in the statute.

Finally, the committee has made quite a few requests for information and that FDA try to obtain certain information, and we will be working to bring that information forward to the full committee as we are able to obtain it. And so we will be providing that scientific information as

we are able to obtain it.

DR. CONNOLLY: Just so I can be sure, you said the full committee. Would you also be referring to the subcommittee, bringing forth more information? If the subcommittee poses questions, will you bring that --

DR. HUSTEN: All information will be brought forward to the committee, and then the subcommittee will have access to it in order to write the report.

DR. SAMET: Greg, this is Jon. I have had some discussion with the CTP about how we make -- what if we need to support particular needs, almost along the lines of a research assistant. I think it's something we'll continue to look at.

DR. HUSTEN: Yes.

DR. CONNOLLY: Thank you.

DR. SAMET: Let's see. Dan?

DR. HECK: Yes. One follow-up question regarding the trade secret confidential information that may go into this report.

Do the owners of the confidential information, presumably some of the major tobacco manufacturers, do they have the power to waive their trade secret concerns about confidentiality in order to enable their representation to have fair and equitable participation in the process?

DR. HUSTEN: We would have to consult with our legal experts on that, and we can try to get that information and get that answer back to you.

DR. HECK: Because I would think that the represented parties would prefer to have a fair place at the table in preparing the report.

DR. HUSTEN: Again, we can check with our legal counsel. That would mean that all information presumably submitted would be -- the confidentiality would be waived. But we can check on that. I think we would still have to be checking to see if there were things of concern. But we certainly will check with legal counsel and get that answer back to you.

DR. HECK: Thank you.

Open Public Hearing

DR. SAMET: Are there other questions? At the moment I see no hands up.

[No response.]

I think perhaps as we move to our discussion of process and how we're doing this, we'll have, I'm sure, more discussion.

Then I think we should move now to the open public hearing. And as I understand, I think we have two public commenters signed up.

With regard to the open public hearing, both the Food and Drug Administration, the FDA, and the public believe in a transparent process for information-gathering and decision-making. To ensure such transparency at the open public hearing session of the Advisory Committee meeting, FDA believes that it is important to understand the context of an individual's presentation.

For this reason, FDA encourages you, the open public hearing speaker, at the beginning of your written or oral statement, to advise the committee of any financial relationship that you

may have with a sponsor, its product, and if known, its direct competitors.

For example, this financial information may include the sponsor's payment of your travel, lodging, or other expenses in connection with your attendance at the meeting. Likewise, FDA encourages you at the beginning of your statement to advise the committee if you do not have any such financial relationships. If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

The FDA and this committee place great importance in the open public hearing process. The insights and comments provided can help the agency and this committee in their consideration of the issues before them.

That said, in many instances and for many topics there will be a variety of opinions. One of our goals today is for this open public hearing to be conducted in a fair and open way, where every participant is listened to carefully and

treated with dignity, courtesy, and respect. Therefore, please speak only when recognized by the chair. Thank you for your cooperation.

I'll remind the public speakers that you have ten minutes. And I will give you -- I guess, actually, are the public speakers there with you, Karen?

[Dr. Husten responds.]

DR. HUSTEN: Yes.

DR. SAMET: Okay. So they will have a time warning. Is that correct?

DR. HUSTEN: Yes.

DR. SAMET: All right. So I won't give you a time warning.

I believe our first public speaker is William True from Lorillard.

Are you ready to start?

DR. TRUE: Yes. Thank you, Mr. Chairman.

Good morning. I'm Bill True, senior vice president of research and development for Lorillard Tobacco Company, and I am speaking today on behalf of Lorillard and R.J. Reynolds Tobacco

Company. I thank the committee for the opportunity to share these comments.

The task before the subcommittee is to prepare a report and recommendation on menthol cigarettes. This report must be based on sound science, and the drafting process for the report must also reflect the scientific integrity.

Since the passage of the Family Smoking Prevention and Tobacco Control Act, the FDA has consistently conveyed its intentions to employ an open, transparent, and inclusive process when determining whether, when, and how to impose regulations on the tobacco industry. The FDA has also stated, in drafting the menthol report, TPSAC will employ a process that is transparent and inclusive, and that the conclusions of the report will strictly rely on robust scientific data.

We believe that subjective or preconceived notions have no place in an analysis founded upon validated, conclusive information developed using sound experimental and epidemiological procedures. Lorillard and R.J.

Reynolds agree with the principles of objective scientific rigor that have been handed down to TPSAC and its subcommittees by the FDA Center for Tobacco Products, as well as the explicit requirements of the FDA governing regulations of advisory committees in general.

Openness, transparency, inclusiveness, and scientific rigor are essential to ensure public trust in the conclusions of the menthol report. These requirements demand that all stakeholders, including the tobacco industry and the general public, have meaningful opportunities to participate in the scientific evaluation and report-drafting process.

Drafts of the reports should be subjected to thorough review and comment by the public and the industry, and TPSAC must follow a schedule which permits the review of drafts and incorporation of submitted concerns.

TPSAC has a diversity of membership, including nonvoting representatives of the tobacco industry. As Dr. Deyton has acknowledged, one

reason for having representatives from the industry is to enable the FDA to understand the industry it is charged with regulating.

To provide TPSAC with the benefit of their extensive scientific knowledge and experience, the nonvoting industry representatives must be provided with a meaningful opportunity to contribute to the menthol report. Importantly, the nonvoting members have valuable expertise, including one who is the most knowledgeable on the science of menthol cigarettes worldwide. Their knowledge and experience is essential to the subcommittee as it works to draft the report based on menthol science.

The vast majority of available science on menthol is not proprietary in nature, and we urge the FDA to reconsider and work with the industry to determine the appropriate balance between industry representative inclusion and trade secret protection.

In addition to following open, transparent, and inclusive procedures regarding

the preparation of the report, a rigorous scientific process must be forward in evaluating the information and data upon which the report is based. As Dr. Hamburg explained, "The FDA regulation of tobacco products is a science-based, science-driven process. It must be."

The use of menthol in cigarettes must be evaluated accordingly. Sound science alone, not inference or speculation, must form the foundation of the menthol report.

To that end, TPSAC is obligated to evaluate all available and verifiable data and studies on the health effects of menthol in cigarettes. The menthol report must be based on defined, rigorous, and objective scientific standards. Those standards are defined in the Federal Advisory Committee Act, the Data Quality Act, and other such guiding principles.

Some of the most significant and advanced scientific studies of menthol have been conducted by the tobacco industry. In addition to peer-reviewed, published scientific papers developed

from this work, a substantial volume of additional information has been produced or presented to TPSAC at the committee's request, and these written and presented data must be considered.

As the public record reveals, TPSAC has undertaken only a cursory analysis of the limited set of scientific data in studies related to menthol to date. As TPSAC prepares the menthol report, it is charged with the development of a sound and independent analysis of the topic and must not rely unduly on information summaries provided by FDA staff that were intended to assist with, and not replace, TPSAC's independent assessment of the studies and data regarding menthol.

TPSAC must conduct a comprehensive, robust, and scientifically defensible evaluation of all the studies and data relied on to draft the menthol report. A single rigorous scientific standard must be applied to the selection and assessment of the studies and data. At a minimum, this standard must include, objectivity in

considering data, evaluation of all available studies and data, consideration for the full spectrum of worthy scientific interpretations of the data.

In addition, strict scientific criteria must be established and used to evaluate each individual study or data set to determine the methodological rigor with which the study was conducted and the validity of the study's conclusions. Only studies and data that provide direct, measurable outcomes which have been evaluated with statistical precision and rigor should form the basis for the menthol report.

Examples of criteria to evaluate methodological rigor and conclusions of published studies include population size, representativeness of population sample, sample selection or other biases, the study endpoint, interventions should be well described, objectively measured outcomes, reproducible results, appropriate statistical analysis, and limitations clearly discussed and reported.

In order for study conclusions to be valid, it is essential that they do not extend beyond what the data establishes, the statistical significance is verified, and the conclusions are fact-based and do not rely on speculation.

Once the quality of the studies and data have been evaluated by TPSAC, scientific standards for determining the weight of evidence regarding the health effects of menthol to individuals or to populations must be used to guide any conclusions reached by TPSAC on the use of menthol. Greater weight must be given to studies that use better methodology.

For this process to be open and transparent, a clear understanding of why studies were included or excluded is necessary to provide the basis for TPSAC conclusions and how each included study was weighted.

This subcommittee has been charged with a difficult task. In addition to carefully and critically evaluating the wealth of scientific data available on menthol cigarettes, the

subcommittee is the guardian of the integrity of the menthol report.

We urge the subcommittee to invest both the time and effort to ensure that it employs a process that guarantees that the menthol report's conclusions and recommendations are reached only after a thorough scientific analysis of all relevant studies and documents.

Clearly, there are many strongly-held opinions about the use of menthol in cigarettes. But if the subcommittee follows the science, using both sound process and sound critical assessment methodology, the menthol report will withstand scrutiny and it will be a scientifically defensible recommendation to the FDA.

Thank you very much.

DR. SAMET: Thank you, Dr. True.

Are there questions for the presenter from the committee? I'll give you a moment to see if any hands come up.

[No response.]

DR. SAMET: Okay. Then we'll turn to our

second public commenter, Jim Tozzi from the Center for Regulatory Effectiveness. Please go ahead.

DR. TOZZI: Mr. Chairman, distinguished members of the committee, I'm Jim Tozzi. I'm with the Center for Regulatory Effectiveness. We take grants and donations from virtually every industrial sector, including tobacco.

I would like to start off my presentation to applaud the FDC -- I testify a lot on financial regulation -- the FDA on the actions they have taken to improve the process. I'm particularly impressed with the statements that were just made on changes in the process by which the report will be written, and we should recognize those.

There are several points in the presentation that you just made that I would like to emphasize, which I think goes a long way to make the process FACA-compliant and participatory and in compliance with not only the letter of the law but the spirit of the law.

The first one obviously is when the FDA representatives stated FDA will not write any

portion of the report. It could not be any clearer. The agency can't say it any clearer than that, and we applaud them.

The other one is the drafts in progress are to be kept confidential and cannot be shared with anyone other than these three people mentioned. That is important because you won't have a lot of ex parte interlopers into this process, and we applaud that.

The third one is that there is a process that the FDA has laid out where new information can be taken in, subject to safeguards, and we applaud that, and we compliment you.

There's two issues that came up in the presentation that I would think the FDA should reflect upon, and one is the date. I think you have a herculean task. I'm dealing with this new financial regulation that's passed, and there's no way the government's going to meet all those deadlines. And I know of no meaningful sanctions that any reasonable plaintiff could take to impart any problems on the agency. So I think you might

consider that.

Finally, on the SGEs, special government employees, that you're going to hire as consultants, we'd hope you'd give due consideration to publicizing those names.

Now, let me move on. I like your little lights; they're so clear.

There's two statutes that govern this proceeding. One is FACA, which determines the governance of the committee, and the other one, as the substance of the Act, is the Data Quality Act.

We've commented at length on FACA, and, as I said, we're very pleased with the movement of the agency in that direction. Let me spend a few minutes on the Data Quality Act and its applicability to this proceeding because I think a lot of scientists are, rightfully so, not up to date on the statute.

First of all, the question's always asked, what is the applicability of the Data Quality Act to TPSAC per se? In a nutshell, they get a pass. They're not a federal agency.

There's nothing in the law that precludes any member of the TPSAC of opining in any way he or she wishes. However, there's one big constraint. The FDA cannot use the reports of TPSAC unless they comply with the Data Quality Act.

So that brings us to what are the requirements of the Act? The requirements of the Act -- the Act did three things. One, it directed OMB to write standards which are applicable to all data disseminated by any federal agency. Then the second, it required every agency in the government to take the OMB guidelines and adopt them to their particular scientific areas. And third, it established a process by which the public could petition for a correction.

I won't go at length, but there's three really operable standards. One is utility, determine the usefulness of the information. The other is objectivity, which I think most members of the panel know a lot better than I, but most certainly it deals with being clear, complete, unbiased, and on highly influential information,

which this certainly will be, reproducible.

Now, what actions has CRE taken in this regard? It's not coincidental that we filed a Data Quality Act petition at timing with the Menthol Committee. And why did we do that? We looked at some of the studies to date, and let me tell you what we did.

FDA identified roughly -- and we've been on the kick that we're not looking at the hard science; we think that issue is resolved. We looked at around 20 studies that FDA identified in the initiation/ cessation area. Out of those, a handful, a small number, were surveys that we didn't really think were scientific, were not science studies, and we came up with around 15.

Out of those 15 studies, we looked at those studies whose titles were the most determinative and most conclusionary, and we analyzed those. We didn't look in -- make any predetermined decisions. So we chose eight of them.

Now, what was the process that we in CRE

utilized to review those reports? First, the reports were given to statisticians around the country, outside of CRE, and asked them to review it. Second, the statisticians' reports then came in to CRE, and a number of experts in CRE, cognizant of the Data Quality Act, wrote up analyses. Then the actual petition was written by me and one other person.

Now, what does the petition say? Basically, what we're saying is that the eight studies that we reviewed, in different degrees, we think, are noncompliant with the Data Quality Act. Now, we in those studies, in our assertions, are obviously subject to public comment. And so, we went out of our way to be extremely transparent on that process.

First, we published the unedited reports of the statisticians on our website, and there's a TPSAC site we have. Second, we asked the public to comment on the analyses of the statisticians. Third, we sent the analyses to the authors of the reports. And fourth, we wrote the petition and

sent it. It's up on the TPSAC site, and it's now undergoing public review.

Now, what was the basis of that? The basis of this is that, really, when you impose the Data Quality Act on a proceeding like this, it's a new game, and not all agencies comply to the letter of that law. But in this case, I think, given the import of this decision, the magnitude of the decision, there's going to be a lot of oversight groups looking at the agency to comply with this.

What are the sanctions if you don't comply? There's an appeal process. There is always intervention by OMB, who oversees the statute. And, of course, there's ultimately now, which some may disagree with, but a movement towards judicial review.

Let me end with one consideration for you also. We summarized in the data quality petition some generic concerns that came out of the studies as being definitive. In no way did we suggest that the studies were useless. The fact that they

don't comply with the Data Quality Act doesn't mean that. A lot of them are pointers. A lot of them are very good signs of things of an initial decision.

What we saw a lot of times was a disconnect between what was in the study and what was in the statements of the conclusion of the study. It was like the print media. You know, in the print media, you often have text editors and you have copy editors and you have headline editors. It looked like, in some of the studies, the conclusion section was not written necessarily by the scientist who wrote the study. We're not sure.

But in any event, we think it appropriate that when you look at the petition, not that every aspect is not subject to review, not that every aspect cannot be questioned by other experts, but the fact it sets sort of a prototype, a protocol, for the type of analysis that FDA's going to be required to do, because FDA can't release the menthol report until they issue what we call a

pre-dissemination review report, where they state in their own internal process that the report is compliant with the Data Quality Act.

Thank you.

DR. SAMET: Thank you.

Let me ask the committee if there are questions for Mr. Tozzi with regard to his presentation and issues raised.

[No response.]

DR. SAMET: So hearing none, Karen, this is our last public commenter?

MR. GRAHAM: No. No comments.

Committee Discussion, Establishment of Timelines, and Writing Assignments

DR. SAMET: I just wanted to verify we have no other commenters there.

Then the open public hearing portion of the meeting is now concluded and we will no longer take comments from the audience. The committee will now turn its attention to address the task at hand, the careful consideration of the data before the committee as well as the public comments.

Now, moving along rapidly, we are roughly, fortunately, ahead of schedule, so I don't think we need a break at the moment. I would suggest we move right along to our agenda and see how we're doing, and then decide how to time the break, if that is okay with everyone.

So we will be moving into sort of the heart of the first discussion of the subcommittee, which would be to talk essentially about how we're going to do our task. And I think between giving us our charge -- and Karen has given us some ideas about how we could be able to report.

Somebody should mute their phone. We're getting a lot of static.

So I think perhaps a good starting point might be the materials that I put together just to give us something to discuss. And that would be, in the meeting materials sent this morning, there is something called "Samet Handout."

Karen, do we have that as slides or something? Somebody presented that?

DR. HUSTEN: We have slides. Did you

want to use those, Dr. Samet?

DR. SAMET: Well, I think it might be useful just to -- either that or people can open the handout, but just as a way of getting started. I think if we begin with sort of the draft report outline, and maybe the figure, I think, just so we have a basis for organizing our thoughts.

DR. HUSTEN: So, I'm sorry, do you want the figure first? I wanted to make sure I was understanding you.

DR. SAMET: Let's start with the outline first.

DR. HUSTEN: Okay.

DR. SAMET: Okay?

So I've put together an outline, in part, so we would have something to start with for discussion because this has -- so take it in that spirit. So, if we could just -- Karen, I can advance the slides, can't I, or Corinne?

MR. GRAHAM: Yes, you can. There you go.

DR. SAMET: Okay. I've got it. Good.

They're somewhat generic, and I'll just

quickly run you through this; so an introduction, no surprise. And I think here one question needs to be answered with regard to menthol, what is a menthol cigarette, and our framing of the report and how we're going to do this.

Moving to the second, at least my correspondence after -- or sections, I think we should have a goal, at least in the body of the report. We may want to rely on appendices for evidence tables.

Then, here, our approach to evidence-gathering and review. How was the literature identified that we reviewed? How did we review it? And then, what was our approach for classifying the strength of evidence in relationship to the questions we want to answer?

A third chapter coming from the writing group, physiological effects, physiological and toxicological effects of menthol; patterns of smoking of menthol cigarettes; the consequences of menthol smoking for initiation and cessation, or smoking -- excuse my bad English here -- menthol

cigarettes for initiation and cessation; effect of menthol and disease risk of smoking; that is, does smoking of menthol cigarettes modify the risk associated with smoking; public health impact of menthol; and then committee conclusions.

So this is a somewhat general outline that I think covers some of the main points that we, obviously, need to deal with. And I think if we went now to the figure -- can I do that?

MR. GRAHAM: We'll pull it up for you.

DR. SAMET: And in the note you're looking at, I've written some explanatory text about this. But this is just sort of a very general diagram, beginning on the left with youth and adolescents not yet smoking, and extending over on the right to disease and death associated with smoking of tobacco products and cigarettes.

Then, along the way, the circles correspond to the questions that I've raised in the text. So, for example, number 2, circle number 2, does menthol cigarettes increase the likelihood of moving from experimentation to

initiation, becoming a user of cigarettes? And, for example, do menthol properties at number -- I guess it's number 5, does menthol influence the likelihood of moving from addiction to cessation?

So this is just a very general framework for thinking about getting organized. And you'll see that I've put together some text corresponding. And again, this is all in the spirit of giving us something to organize our discussion today.

So remember that by the end of the day here, a goal is to have identified what our chapter outline is, more or less. I recognize that this could be who wants to contribute to which components of the chapter, and have some idea about how to move forward.

So let us start with this, and I'll open up the discussion. I see, Greg, you have your hand up, so to speak.

DR. CONNOLLY: Let me just start, and I'll try to go through the outline for the menthol report.

I think it would be worthwhile defining public health impact to understand number 1. Number 2, you say the strength of the evidence, but I still think there are question marks about what is the evidence. I'd be curious in the FDAAA Act how evidence is defined or how FDA gathers its evidence or internal documents from the tobacco industry. I think there's a wealth of information; is that considered evidence?

When the FDA looks at drugs in their reports to the health -- that aren't published in the scientific literature, does that become evidence that the committee would take a look at?

When you talk about 3, physiological effects of menthol and toxicology -- and I think this generally runs through the document. The document seems to be, and in the chart, speaking about disease risk. You say menthol experimentation to disease risk. But, in reality, it would appear that the statute is separating out abuse potential, that is, abuse liability, how does nicotine contribute to dependence, which is a

correlate with initiation and the lack of cessation. And then, in other sections, probably more in the MRT section, MRTP, we're discussing disease risk. And I'm wondering if we should try to differentiate between abuse liability and disease risk, and have a clear focus on abuse liability and the role of menthol in abuse liability.

We do have a section, Menthol and Disease Risks under 6. I have to go back and look at the definition of public health under the statute, maybe under Section 907 or 906, to see if that's where the statute is directing us. But I think some thought should be given to that.

Number 7 is sort of the summary of what we've done from 1 through 6. You could put it as number 1, but I think the way you've done it is fine.

On the chart, the chart still is the disease model. It ends with the concept of disease risk. I think we could add disease risk to abuse liability.

Under Menthol Properties, 2, you use the taste. I think at the last meeting, we had a very interesting discussion with the industry on the issue of taste, if it was a gustatory action, or is it a much broader issue of chemosensory perception of tactile receptors and olfactory receptors. So I'd just drop taste. I don't think you have to qualify taste in experimentation. But menthol properties, do we have to define them, what we're really looking at?

So I think --

DR. SAMET: Greg, stop for a moment.

DR. CONNOLLY: -- I would finally say that we had one meeting --

DR. SAMET: Greg, let me break in and just say, my words here are more in the spirit of placeholders than specifics.

DR. CONNOLLY: Okay. I'm just trying to point out just ways to strengthen what you've done. I think what you've done is excellent, and I'm not criticizing it. I'm just trying to strengthen it, but try to provide a balance

between dependence and between disease risk.

I would finally say, Jon, that we did have a first meeting where we set up -- we really developed four basic questions for industry. I thought we arrived at a pretty good consensus. We spent a lot of time on that. And those four categories captured what you've done here. But also probably in a different way, it wouldn't hurt to go back in and look at the consensus we already arrived at in developing those questions so that we have some continuity with which consensus we've achieved before. And the questions are in the Federal Register, and they're the ones that the industry would be asked to respond to.

DR. SAMET: Let me make a request that -- ask Corinne if you can put those back up at some point, just to give us a reminder of where we had arrived at. Just one other point. In the memo that goes over with this, there are questions posed both at the level of the individual smoker and then around population health impact.

DR. CONNOLLY: Well, I thought we'd

discuss that next, Jon.

DR. SAMET: Yes. And again, I think we have some questions about how we will engage --

DR. CONNOLLY: I would like a discussion of the next memo also.

DR. SAMET: Yes. Neal?

DR. BENOWITZ: Can you hear me?

DR. SAMET: Yes.

DR. BENOWITZ: I've got two questions that came from Corinne's instructions.

First is the question of benefits if the person is at risk. We haven't talked about benefits. I think in the discussion, we need to define what we mean by benefits.

The other issue is the question about contraband, how we're going to deal with that.

DR. SAMET: Okay. Good point. So let's describe contraband.

Dan?

DR. HECK: Yes. I would endorse Dr. Benowitz's suggestion that the unintended consequences be fully embraced or discussed, to

the extent that we're able to do that.

Mr. Chairman, I just want to enter again for the record my concern about the exclusion of the industry representation in this report development process here. By looking at the chart here, I see any number of areas where there's a wealth of information resident in the industry and the industry's representatives. And I think that the hypothetical concern that trade secret issues might be raised is really not substantial enough as a blanket starting point to consider that the representation should not have an active play (unclear). Thank you.

DR. SAMET: Dorothy?

DR. HATSUKAMI: Did you call my name? I'm sorry.

DR. SAMET: Yes, I did.

DR. HATSUKAMI: Oh, okay. Great. Thanks.

I noticed that one of the areas that was missing in the outline was the whole marketing efforts. And I was wondering if you thought that

maybe they were subsumed under the consequences of menthol smoking for initiation or whether it was just an omission, a deliberate omission. So that was one of my questions.

I think, secondly, I think it would be worthwhile having some discussion in terms of what criteria we're going to be using for strength of evidence because I think that's going to be really critical for looking at or examining the studies that are at hand.

So those are my concerns.

DR. SAMET: Yes. I obviously agree, and I think in my discussions about this with FDA will certainly be for this subcommittee to make recommendations on criteria for strength of evidence to TPSAC. And what I think is particularly important, obviously, is setting a precedent in terms of how TPSAC will approach the evaluation of evidence. So I think we need to put some careful thinking into this.

Karen?

MR. GRAHAM: By the way, Dr. Samet, just

to let you know, Dr. Lauterbach has his hand up here in the room as well.

DR. SAMET: Okay, thanks. I'll get to that, Tom. Thank you.

Karen?

DR. LAUTERBACH: Dr. Samet, I just want to express by concern, the same as Dr. Heck did, about the exclusion of the industry representatives.

DR. SAMET: Thank you, John.

Karen, are you ready?

DR. LAUTERBACH: I'll just point out here, I spent 24 years in senior R&D positions --

MS. DELEEUW: Can you hear me?

DR. LAUTERBACH: -- with the House of Menthol, the manufacturers of KOOL. And I just feel that at no time -- when I asked the officials of the Center for Tobacco Products about this committee, at no time did they intimate or say that we would be excluded in the manner we're being excluded.

DR. SAMET: Let me ask, before we leave

this point, if Karen or Corinne have any further comments on the industry representatives.

DR. HUSTEN: Again, the issue was brought up. And, as I mentioned, we'll discuss with our legal counsel what ability we have around the trade secret and commercial confidential information, for industry to waive that.

DR. SAMET: Let's see. Karen? I think you're up.

MS. DELEEUW: Thank you. In looking at the model you presented, which I agree is a fabulous start, I would just like to make the point that perhaps there should be some arrows drawn between the non-menthol and the menthol boxes to indicate that there may be some switching going on along the way, so that not all the people who initiate with menthol stay with menthol and vice versa.

DR. SAMET: All right. Thank you. And, let's see, let me go back. Greg?

DR. CONNOLLY: I agree with Karen. I think it would be -- in the last meeting with

industry, what we should have inferred is there could be a potential -- not for cohort effects with menthol brands, but rather switching, sort of strengthen that; you know, menthol goes on to not menthol smoking.

The second thing we grapple with is many of the public presentations that dealt with issues of equality, which go beyond science. But I think one of the overarching statements in the law are looking at high-risk groups, minorities, and the science that applies to high-risk groups.

I think, given the history of the FDA, it would be good on the statute -- I mean, on this report -- to factor in high-risk groups; that would be blacks, young people, in the model. And I think that could come in -- you use the term "youth/adolescence," but I think issues of equality, and the science base for that, being the targeting of high-risk groups through marketing and use.

DR. SAMET: Right. And in fact, Greg, I'd considered offering that there ought to be

perhaps separate diagrams for different groups. And that's something we may want to think about because this is highly generic and does not reflect the different responses to menthol for different populations. So I think we need to think about how to handle that.

Let's see. Dan?

DR. HECK: No. I didn't have my hand up.

DR. SAMET: Oh, you didn't have your hand up?

DR. HECK: I'm sorry.

DR. SAMET: That's all right; whatever.

Patricia?

DR. HENDERSON: Yes. I just want to concur with Greg -- hold on. There's a lot of feedback in my phone.

Can you hear me okay?

DR. SAMET: Yes. We can hear, but you are echoing.

DR. HENDERSON: Yes. I'm not sure what's going on. But I just wanted to concur with Greg that we definitely need to look at certain risk

groups, differently from the model that you have given. And if we can produce certain models, different models, for them, I would really appreciate that.

DR. SAMET: Or the same model, but the risks or the transitions are different from population to population.

DR. HENDERSON: Right.

DR. SAMET: I think it's another way to show that. Yes. No, I recognize this is quite generic.

Let me ask, are there other general comments?

[No response.]

DR. SAMET: So one other thing we might do -- let's see.

Tom, could we go to the handouts, my written text?

MR. GRAHAM: Okay. The notes or the outline?

DR. SAMET: Yes. The notes, the outline. The memo was in the material that Karen sent this

morning. But I had listed out some questions within the body, related to individual smokers and related to population impacts. And so here are -- I think there were maybe five related to individual smokers or four. I can't remember.

So these are some of the questions for which we -- again, this would go back to chapter 1, formulating the questions we're going to answer with the available evidence. I would note -- I think it's Dorothy who mentioned marketing, how we factor that in. I think it's important. So questions related to individual smokers here.

Here are the other three. And so these relate to individual smokers. And then there were questions related to population impact, and here are the marketing questions.

So, I think the kinds of questions, again -- I'll just take this as a start -- that we would be putting into chapter 1 to frame what we are going to try and answer with the evidence reviewed. So I think, ideally, we have sort of an agreed-to general figure that is our "framework,"

and that we then have questions related to that framework.

We review the evidence and provide our answers with regard to the extent of evidence available and its strength in supporting conclusions related to these questions, and then that leads to our overall conclusion. So sort of a very general approach, I think, is how I see us succeeding, and obviously, with a huge amount of effort to identify the evidence, evaluate it, and draw conclusions about it.

So let me again open up for discussion, and I think as our writing groups begin their work, they'll of course be refining everything. So, again, what we need to do today is to leave the discussion with agreement on general approach. And I would hope some leaders to take the lead in different writing subgroups.

So again, let me open up for comments. Let's see. Greg?

DR. CONNOLLY: Can you hear me now, Jon?

DR. SAMET: Yes.

DR. CONNOLLY: Okay. Under Overview, the first line, you state as to whether it should be banned. I don't see anywhere in the statute that term used. And at the last meeting we discussed a number of options, including fixing levels --

DR. SAMET: Right.

DR. CONNOLLY: -- phasing it over time, or even allowing compounds with a gustatory effect but no chemosensory effect. So I think you could --

DR. SAMET: Yes. So that should be modified.

DR. CONNOLLY: Yes. A substitute term.

Then under the fourth line, "This information has come from literature review," I think again we need clarification about what we mean by literature. Is it only published scientific literature or is it from other sources?

DR. SAMET: Right. You know, actually, let's stop on that point because I think this is something that, again, will need some general discussions. There will be multiple lines of

evidence that we will have at hand, and I think what we need to do is identify how we have found that, whether it's the peer-reviewed literature, industry documents, survey data.

I think what is important here is -- the comment here is about what we've been provided to date. I think what we really need to do is to sketch out our approach moving forward.

DR. CONNOLLY: Jon, I would ask FDA to provide guidance to us from other committee action or the FDAA Act in terms of what they consider to be admissible evidence.

DR. SAMET: That would be to Karen.

DR. HUSTEN: This is Corinne. It's up to the committee to decide how they want to weigh the evidence and what they want to include and not include.

DR. CONNOLLY: Jon, do you want to set an agenda item for the next meeting to discuss that?

DR. SAMET: Yes. No, clearly this is one of the things. Again, I think what is important is that we want to consider all relevant evidence

that we can get our hands on, recognizing that we have a constraint in time frame that is, I think, already discussed; and that we state very clearly where the evidence comes from and what is the approach that we use to gather it. And I think that's sort of the standard of practice now.

DR. CONNOLLY: I think that sounds acceptable to me. We could put that in place.

DR. SAMET: Yes. Let's see.

Greg, did you have another comment?

DR. CONNOLLY: Yes. Now, under the second paragraph, line 2, defines points at which the availability of menthol in cigarettes could harm. Again, if you look at the statute, talking about population effects on initiation and cessation, it speaks to dependence and relates to dependence. And I think the point that comes up is what is the relationship between menthol products and dependence. So it comes back to abuse liability. And there are in other statutes -- I think the Controlled Substances Act -- where FDA takes the first pass, they will

look at other ingredients that affect the principal drug agent.

So I would recommend adding -- we could add "harm" or contribute to "dependence."

DR. SAMET: Yes. Here harm is meant in the broadest context. And again, I think these are the things that the workgroups will define.

DR. CONNOLLY: Yes. I'm just trying to -- I think you've done an excellent job, and I'm just trying to be helpful.

DR. SAMET: Yes.

DR. CONNOLLY: I think, Jon, if you could explain the rationale why we break out individual smokers for population effect -- I just want to understand that better. And under individual smokers, could we add the concept of high-risk groups? And then, also, abuse liability begins with the smoker.

But I'm just looking at what we've done in the past and the statute, and just trying to grapple with the concept of how do we apply time to an individual. So if you could just explain it

so at least --

DR. SAMET: Well, I think this is -- and part of the attempt, using the diagrams, is to think about how the availability of menthol cigarettes might influence some of the very generic steps in this framework. It's the integration across that, that results in sort of the population-level impact.

So this has to do with issues that are particular to what happens in an individual; for example, number 6. And I think, in part, this becomes questions that might be addressed through review of the literature versus some of those that are at the population level, based on model results. I think those are some of the distinctions I've made.

Again, this perhaps may appear arbitrary to an extent; again, just something to get us organized.

DR. CONNOLLY: Just a comment. When I think of individuals, I always begin to think of a mechanistic link, which we found at the last

meeting that -- I think it's unclear about the exact mechanistic link for menthol impact. We don't know the mechanistic link for adenocarcinomas in lung cancer.

Could we talk about related to youth and smokers just so that we don't bracket ourselves in such a way with a term like "individual," but we say related to youth and smokers?

DR. SAMET: I'm open to all modifications.

Let me go on. Let's see, Dan, you have your hand up?

DR. HECK: Yes. I'm at a certain disadvantage here because I do not have the meeting materials, other than the slide that is currently displayed on my screen, which is related to individual smokers.

Just a general cautionary note. I see four listings here for causation of menthol by various behaviors here. And I just want us to recall that, from observational and cross-sectional or spot surveys, we cannot draw the

sorts of cause-and-effect conclusions that I think are suggested in this rating here. But, again, this is the only slide I see.

DR. TEMPLETON-SOMERS: Dr. Heck, there aren't slides in your e-mail for this? This information is in your handout from Dr. Samet, in the notes.

DR. HECK: Was that sent --

DR. SAMET: That was an e-mail sent out this morning, Dan.

DR. HECK: Okay. I don't see it here.

DR. SAMET: You should. Let's see. This is the one that says "Samet Handout," I think.

DR. HECK: I just don't see it on my e-mail here, but we can talk about that later.

DR. SAMET: Yes. And I will comment -- and I think this goes back to this committee approach. I mean, I think the question of what one learns from observational studies about mechanisms and causation will be openly discussed. I think observational evidence, along with other lines of evidence, will be a principal basis for

inferring how the presence of menthol might affect one or more of the steps in the framework; because, obviously, experimental data are not going to be available.

So I think the group on evidence review will need to state exactly how we are approaching this issue and how evidence, whether observational or experimental, biological, will be brought together for a supporting conclusion.

Let's see. Karen?

MS. DELEEUW: Thank you. I'm not sure if this relates to the individual or the population effect. But one of the things that continues to intrigue me is our job in public health is to make smoking more difficult. And the question I continue to have is if menthol cigarettes are not available, what percent of menthol smokers will switch to non-menthol and what percent of menthol smokers will, for whatever reason, see this as an opportunity to quit smoking? Because, again, we've made smoking more difficult for them.

DR. SAMET: These are the population type

questions.

Well, if we could go back -- let's see. Greg, I see you have your hand up again. Okay?

DR. CONNOLLY: I think what Karen was intimating, and correct me if I'm wrong, is that we're not asking questions, which we heard so many public presenters talk about; does menthol contribute to the ease of nicotine dependence? Does it affect perception or risk of inhalation, of reward?

Those all then relate back to what you've written, with the exception of access. We're still missing the real central question here; what is the specific role that menthol plays in initiation of dependence? Does it affect certain receptors, whether it be thermal impact, to make it easier to become dependent upon cigarette smoking so that initiation occurs easier, and then can switch up to a non-menthol brand or a higher-menthol brand; or does it make it harder to quit because of the menthol brand?

Those are key questions that are not

captured. And I think what we're capturing are questions that are interesting, but maybe a little bit adrift from the statute is trying to get at.

Karen, if I misinterpreted you, I'm sorry and you can clarify.

MS. DELEEUW: No. I think that was an excellent interpretation of what I was saying. And I think, in addition to that, what I understand from smokers is they identify themselves as either menthol or non-menthol.

So I think there's some other piece of it in terms of smoker identification that is not as specific as brand loyalty, but has something to do with the fact that they see themselves as a menthol or non-menthol smoker, and how can we interrupt that.

DR. SAMET: Mark?

DR. CLANTON: Am I online?

DR. SAMET: Go ahead, Mark.

DR. CLANTON: I have a question that may even transcend the time frame for this particular report. I think we're producing this report at

this time not so much because there are adequate conclusions about data and science and menthol but because we have a mandate to do so. And I want to understand what kind of pressure is on this report in terms of using the report for regulatory purposes. I wanted to ask that because it would seem to me that as science advances and we learn more about menthol and nicotine and carcinogenesis of disease, even after the report is published, I want to know and make sure that this committee gets a chance to come back and consider menthol in light of new evidence. Or, in fact, are we sort of bound, is FDA bound, by the report that we're going to produce on the time frame we're going to produce it?

Does that make any sense?

DR. SAMET: Let's see. Corinne or Karen, do you have a response to that?

DR. HUSTEN: The statute provides a time frame for the TPSAC to produce a report. There's no specific time frame for FDA action. And I think it's like any part of regulation, as science

evolves, the potential approaches then evolve.

DR. CLANTON: Okay. I think that is responsive to my question, and it also gives me some sense of flexibility and relief. So we'll certainly construct the best report possible, given the time frame. But when it's appropriate and necessary, the issue of menthol and public health can come back to this committee for us to review that and offer FDA contemporary or contemporaneous advice.

DR. SAMET: Dan?

DR. HECK: Yes. I think I'd agree with you, Mark. I think it's very important that this particular committee at this particular time not overextend its interpretation of the available data. The available data are what they are. It is not conclusive in all areas. And that's the snapshot that we should reflect, where appropriate, in our concluding report.

DR. SAMET: Greg? Greg, did you have your hand up again?

DR. CONNOLLY: Hi. Can you hear me now?

DR. SAMET: Yes.

DR. CONNOLLY: Okay. I'd like to agree with Dan and just say that if we find there are holes in the science and more science is needed, a rule of precaution may be wise to protect high-risk groups in the American public health until more information comes in. And then we can revisit that, and the rule of caution could be recommended action if there is something out there where there -- but again, have to go back and look at the statute to see what the authority is.

Number two, I know the FDA and CTP is under very strict constraints by the statute to get things done. But I think, in that process, I don't want to see us as a mandate or as a timeline, but truly as a group of individuals who have arrived at consensus at the first meeting, who are knowledgeable about this area both from our community-based experience, our experience in research, our knowledge; so the overall statute, so when and if FDA takes action, that we're speaking as a group and just not satisfying a

particular date in a statute.

So I would urge -- and maybe it's something we'd want to consider in the report -- that there be some revisiting as new science emerges. And again, cautionary principles, particularly given the history of the FDA, are oftentimes warranted in looking at a recommendation issued.

DR. SAMET: Okay. I think this has been a good general discussion. What I'm going to propose -- we've got some very specific things we need to get done. And I think we might take a -- how about a 10-minute break? And then what I would suggest is we regroup, and then let's go back to the outline and start putting names on it and talk about some specifics around moving ahead.

There are an awful lot of big issues here that we could wander through, but we've got some specific things to get done. Actually, let me ask Tom or Corinne, what should we all do? Hang up and dial back in? Is that what you want us to do?

DR. TEMPLETON-SOMERS: I think you can

just mute your phones and walk away for 10 minutes.

DR. SAMET: Okay. So mute your phones and walk away for 10 minutes, refill coffee cups, and then we'll be back on. Let's see. So that would be at quarter of. Okay?

DR. TEMPLETON-SOMERS: We also would ask that if you're on a cell phone, if you could please try to move to a land line. I think you'd get less interference. Thank you.

DR. SAMET: So 10 minutes.

(Whereupon, a recess was taken.)

DR. SAMET: The subcommittee respected the 10-minute deadline, so we have already had some discussions. And just to perhaps recap, I would suggest that we go to the outline and start with both comments about the different chapter segments and then recruiting people to be on them.

I think one point that needs to be addressed, Greg had some comments to make about particular aspects of our response to our charge. Let's see. Dan had made a comment --

Dan, do you want to repeat your comment now that Karen's on the line?

DR. HECK: Yes. With the discussion of the recruitment of the groups to develop the different sections of the report, I wanted to offer my services on any and all of those areas unless or until there is a determination that there are indeed some kind of trade secret issues that may disqualify me from those processes.

DR. SAMET: And my response to Dan is simply that FDA would have to speak to this issue. Appreciate the offer.

DR. HECK: Thank you.

DR. SAMET: So Karen, do you have any comments on this?

DR. TEMPLETON-SOMERS: We'll have to consult with the Office of Chief Counsel and see what can be worked out.

DR. SAMET: Okay. So my suggestion would be if we could go to the component of the note I wrote that has, again, this very general outline in it. And, again, as a starting point, Greg --

and I think this goes back to your comment -- I think each subgroup will certainly have the opportunity to reshape the content when we get to the specifics. And I think that's part of the process we need to come up with; in other words, what are the specific details that go under each of the chapters, specific guidance to be addressed, and how does this relate back to the overall framework.

So if we could go back to the outline comment. And right now, I don't think the handout -- I think we've dealt with both Mark and Greg for now. I don't think anybody has their --

DR. TEMPLETON-SOMERS: Dr. Lauterbach would like to speak.

DR. SAMET: Okay.

DR. LAUTERBACH: Dr. Samet, I just wanted to second what Dr. Heck said, that I'd be more than happy to participate in any writing, should the FDA permit that.

DR. SAMET: All right. And again, these are proposed -- my 1, 2, and 3, and so on, these

were proposed chapters, sections, whatever they're going to be, of the report.

So I think that number 1, the questions to be answered -- and, again, there could be any number listed here. Corinne just had a comment that reminded us about the links to the statute and number 2 almost go together. I think, if I understand our ability in terms of the approach to evidence-gathering review of, yes, we can look at what FDA has done, I think there are many standard approaches and guidelines and guidance on how to carry out transparent evidence-based reviews.

So one suggestion might be that the same group takes on what are listed under number 1 and 2. So let me pause here for discussion.

Greg, focusing in on 1 and 2.

DR. CONNOLLY: Okay. Number 1, I would add the statute and previous questions raised by the committee. So two points, one, the statute, and two, what we decided at the first meeting. I thought we'd spent a lot of time and got a lot done.

Number two, Jon, I think that's a separate issue. It's based on FDAAA, other actions -- and it's the expertise of Jon Samet. I trust you implicitly on 2.

DR. SAMET: Yes. No, I thought I would probably take the lead on that one. I think -- and again, I've just had only preliminary conversations about this. I mean, there are so many -- there are a number of extant approaches and systems for kind of doing our tasks. I think what's clear to me is that we need to have one that's transparent.

Let me ask at this point -- one thing that we might do is start to think about who is interested in participating in these subcommittees. We heard from Corinne and Karen about our process of having, I think, two or three people working on each of these sections, I guess.

DR. TEMPLETON-SOMERS: Yes. It shouldn't be too many.

DR. SAMET: So I would certainly volunteer myself to be involved in 1 and 2, and

perhaps taking the lead.

Who else would like to be involved in this? And again, I think there's some obvious -- sort of the time to go through this in terms of expertise.

DR. BENOWITZ: Can you hear me?

DR. SAMET: Yes. Yes, Neal. Go ahead.

DR. BENOWITZ: I'd be interested in 3 and 6.

DR. SAMET: Okay. And I think this goes -- so why don't we just -- let's see. Tom will sort of add names as we begin to fill in.

Let's see. Mark?

[No response.]

DR. SAMET: Mark?

DR. CLANTON: Okay. Working with technology; 5 and 6.

DR. SAMET: Greg?

DR. CONNOLLY: I'd like to change number 8 to recommendations from the subcommittee, as called for in the statute. I think I could be helpful there. I think we also should think about

menthol cigarettes and nicotine dependence, abuse liability. I think I'd be interested in that. I think there are other members of the committee that are expert in that area.

DR. SAMET: Let's see. Let me run back through --

DR. CONNOLLY: I'm adding a section, Jon. I'm sorry.

DR. SAMET: Right. This is just my opinion. So let me see if -- so on 8, you want call this Committee Recommendations?

DR. CONNOLLY: Yes. That's what the statute says.

DR. SAMET: Yes. I probably would say it's Conclusions and Recommendations.

DR. CONNOLLY: Maybe the entire group should work on conclusions and recommendations.

DR. SAMET: Yes. We probably will be, yes. Again, I'm, in part, thinking about the drafting of subcommittees.

DR. CONNOLLY: I would say on 1, Jon, what questions -- maybe the entire committee

should review -- the entire subcommittee review the questions, because they're going to be critical to the framing of the answers, and then on conclusions and recommendations, the entire committee.

I would be interested on menthol cigarettes. I think we should be clear -- and abuse liability of nicotine.

DR. SAMET: Let's see. Just as a comment, I think on ones where -- I mean, obviously the whole subcommittee, and then TPSAC, in the end, will have to review, evaluate, and approve what is written. I think, again, what I'm thinking about, Greg, where you're suggesting that the whole subcommittee be involved, I think still, again, we need a group that will take on the responsibility of the initial writing and drafting, putting forward what the subcommittee will review.

DR. CONNOLLY: Jon, you also had physiological effects of menthol under 3, and toxicological effects; and then as number 6,

effects of menthol on the user.

Would the end of 6, toxicological effects, better fit with -- the end of 3 better fit with 6? So that's physical harm. And then under 3 create pharmacological, abuse liability, dependence, nicotine effects.

DR. SAMET: So let's see. If we go -- is there somebody -- let's see. We've got number 3 in front of us right now. If we took toxicological effects, and I'm just going to move forward, which I think is quite reasonable, would be to put that with 6. So this is essentially observational and toxicological evidence.

So, yes, this one could become toxicological and observational evidence on disease risk of smoking menthol cigarettes.

DR. CONNOLLY: And then go back to 3. On physiological effects of menthol, maybe add abuse liability, nicotine dependence. I would be happy to serve in that group, and I'm sure there are others on the committee who could contribute.

DR. SAMET: That's 3.

DR. CONNOLLY: Three.

DR. SAMET: Yes. Okay. Let's see. We've got a bunch of hands up. So, let's see, let's start with Mark.

DR. CLANTON: I didn't know if there's a limit in terms of how many you want to participate. My primary interest actually is in 6 and 7. I'm happy to do 5, 6, and 7; but 6 and 7, I want to contribute to those reports, that part of the report.

DR. SAMET: Six and 7? Okay. And again, let's see where we are as we start with our initial listing.

Let's see. Dan?

DR. HECK: I think I'm kind of agreeing with what Mark said. I'd see 6 and 7 kind of naturally lumping together; epidemiology and the public health impact are interwoven. On the other hand, with number 3, the toxicology, that section could include the available animal and other toxicology information, as well as smoke chemistry could be woven in there, too. There is some

literature on the effects of menthol on smoke chemistry that might fit into number 3 better than anywhere else.

DR. SAMET: Number 3. And for the moment, at least in terms of health risks, the proposal, I think, is number 6 would be toxicological and epidemiological evidence related to risk. But I agree; probably 3 is where chemistry would go.

Let's see. John Lauterbach?

DR. LAUTERBACH: Yes?

DR. SAMET: John, did you have a comment?

DR. LAUTERBACH: No, I didn't.

MR. GRAHAM: No, he does not have a comment.

DR. SAMET: Oh, okay. I'm sorry.

Dorothy?

DR. HATSUKAMI: Yes. Number 3, the physiological, pharmacological, and abuse liability effects of menthol, is that what it's --

DR. SAMET: That seems to be what it's evolving into.

DR. HATSUKAMI: Okay. I think I can volunteer for that. I still don't understand Greg's suggestion in terms of bringing in nicotine abuse liability, but I certainly would be willing to serve on that group.

DR. SAMET: No. I think you've covered that under 3. I would agree that's number 3. You covered that.

DR. HATSUKAMI: Number 5 I could probably help out on as well. And I'm wondering whether marketing is going to be part of that, related to the initiation, or whether there's going to be a separate group for marketing.

DR. SAMET: So let's figure that out because I think we may need an additional section, chapter, that is perhaps marketing and special populations. I'm not sure we've got that covered sufficiently.

Patricia?

DR. HENDERSON: Yes. I apologize. My phone doesn't have a mute option. Number 4 and number 7, please.

DR. SAMET: And Karen?

MS. DELEEUW: Number 7, and then if we do do a chapter on marketing and special populations, that would be great.

DR. SAMET: And we probably need to.

MS. DELEEUW: Yes. I would agree with that.

DR. SAMET: Let's see. Dan?

DR. HECK: Just a comment for discussion, while we're trying to delineate these. I had the same difficulty in writing my own review on menthol earlier, and that is the smoking topography, the biomarkers, and smoke behavior studies are all kind of intertwined. And I don't know if it would be useful for the committee to maybe identify where the biomarker studies that are available might be discussed in depth.

DR. SAMET: So one suggestion we might do is to go back through the outline. We put some names down. I think one thing that we can talk about and schedule a process, as probably the first step, each group writing an expanded outline

of what they want to take on.

Let me go back. I think Patricia?

DR. HENDERSON: Yes. I'd just like to say, if there is a group for special populations, I'd like to be part of that as well.

DR. SAMET: All right. So let me suggest that we go through -- so we have this number 1, which I think would, again, be more than an introduction. It would sort of set out our overall schema and how and why -- around which we would organize the report to say how we've come to the way we're doing it.

Let's see. I'm willing to take the lead on this. I'll need some help on this.

So who's interested in working on number 1?

[No response.]

DR. SAMET: A profusion of volunteers here.

DR. CONNOLLY: I could help you, if you and I can get along.

[Laughter.]

DR. SAMET: Oh, let's be friends. Okay.

So that was Greg. And maybe -- Dorothy, would you join in this one?

DR. HATSUKAMI: Yes. I would be happy to.

DR. SAMET: Thank you.

Dan?

DR. HECK: I don't want to clutter up our agenda here with comments that have already been made, but I feel like my hands are a little bit tied here. I would like to, and I feel like I'm quite well-qualified to help with a number of these, but until we get a determination from FDA on the appropriateness of that --

DR. SAMET: Right.

DR. HECK: -- I'll remain silent for now. But I could see myself helping with a number of these sections.

DR. SAMET: Okay. Well, we'll note your interested, and that of John -- and we'll wait to hear from the FDA.

DR. HECK: Yes.

DR. SAMET: So on number 1, if you could add Dorothy. And again, so this would involve the framing and refinement of my first crack at having -- okay. And again, whoever is keying, if that's Tom or whoever, if you could add Dorothy to this, just so we don't lose it.

Let's see. Mark?

DR. CLANTON: I'm perfectly happy to contribute to number 1 as well. And I'm just trying to avoid, I guess, all of us being represented on each one. I think, to some degree, we could. But I'm happy and would be capable of contributing to number 1 and also on the issue of special populations.

I do want to say, on that one issue of special populations, we may need to make some decisions about whether it fits under number 7 or whether it merits its own chapter. But at some point, there's going to be some redundancy between talking about public health impact and then impact on special populations. But I'd like to participate on those two as well.

DR. SAMET: So let's keep that in mind. I think your point about keeping the writing groups to a small size is important because, among other things, we're going to have some, obviously, telephone conference meetings. The more that are on, the more difficult it is.

Dorothy?

DR. HATSUKAMI: I would think that special populations might be a cross-cutting theme, across all the different topics. And so I think we need to keep that in mind as well, that there could be a special chapter on special populations. But I think we also need to think about how each of the topics might address those issues.

DR. SAMET: Good point.

Let's see. Greg?

DR. CONNOLLY: I think under 1, if you have four contributors, that strengthens the subcommittee's activities, even though it may mean difficulty (unclear) scheduling. The same would apply to conclusions and recommendations. So as

we begin to develop a consensus based on a broad-based group, I wouldn't be afraid to do that.

DR. SAMET: Yes.

DR. CONNOLLY: And then also, I agree with Dorothy that special populations, because of issues of the quality and science, it's difficult to say they're separate, that we need a science that goes through the entire report. But I still think that doesn't rule out the section on special populations, given the importance of this job to the American public and the populations who use this product (unclear).

DR. SAMET: Okay. Let's go to number 2. So right now, there's my name by that. I don't think we need a huge group for this, but probably someone else who's sort of worked on systemic review processes.

Volunteers? I can't look around the table and see who's hiding, not wanting to be on this.

[Laughter.]

DR. SAMET: But anyone interested?

DR. HUSTEN: Jonathan, earlier you had talked about number 1 and number 2 potentially being combined.

DR. SAMET: Being together. Yes. Well, I think it's a good -- yes. So why don't we try that? Dorothy has certainly worked on these kinds of reviews, and Neal and -- Neal, were you on number 1, I think?

DR. BENOWITZ: Pardon?

DR. SAMET: No. You were not on number 1. Okay. Good.

DR. BENOWITZ: Jon, I'd just make a point. It's Neal.

DR. SAMET: Yes.

DR. BENOWITZ: We really have to just follow number 2 before we start writing. I think we have to be able to classify.

DR. SAMET: Well, yes. So yes, I see number 1 and number 2 as having to proceed very quickly. I think the groups can certainly do their -- begin to develop their outlines and also think about their approaches to gathering

evidence. So I think things can go on in the meantime. But I agree, number 1-2 is critical. Agreed.

So let's say that the names that we have by number 1, which is now, I think, Dorothy, Greg, and myself, plus/minus Mark, will move forward with the tasks under 1 and 2.

So let's go to 3. This is the one that's now rewritten, with toxicology going into 6. And, let's see, Dan made a comment about chemistry here, and there was a discussion by Greg about abuse liability as coming under this one.

We have three people lined up, Neal, Dorothy, and Greg. And I will say we probably should identify leaders on each of these. And I'd be willing to do so for 1 and 2. Maybe, Neal, would you be the right person to do this one, perhaps?

DR. BENOWITZ: Yes. I'd be happy to.

DR. SAMET: Thank you.

Let's see. Greg, a comment here?

DR. CONNOLLY: Jon, I think in terms here

of chemistry that if it's chemistry related to harmful constituents, that would better belong under 6. If it's chemistry related to chemosensory effects, that would be under 3. Why don't we just leave it as Dorothy explained 3? I thought that was a good synopsis, and then place chemistry on harmful effects under number 6. And Dan, unless you object strongly --

DR. SAMET: That's fine. I think this will be part of each group developing their detailed outline. But perhaps we can make a note again here about -- chemistry goes where it should, I guess. And let's make a note also that Neal agreed to take the lead on 3.

So let's go to 4. So this would be a chapter that would be, I think, maybe a compilation of some of the descriptive materials we've been presented with, obviously, with drawing out the implications for particular populations, special populations.

So here we have, so far, Patricia. We probably need at least one more person on this

one.

DR. CONNOLLY: Jon, I wouldn't mind contributing in a minor way, reviewing and adding. But I don't want to overburden my presence.

DR. SAMET: Yes. Well, let's note Greg. But I think -- let's see.

Karen, is this one that you'd be interested in?

MS. DELEEUW: Sure.

DR. SAMET: So let's add Karen, and then Greg in small letters.

[Laughter.]

DR. SAMET: All right. Let's go to 5. So there's Mark and Dorothy. And these subgroups, two may be just fine. It certainly will make conference calls easier.

DR. CONNOLLY: Jon, would this go under 3, since we're talking about initiation and cessation?

DR. SAMET: No. I would actually -- I would think not because I would think this is big enough. I guess I see 3 as more on the physiology

side, and this is on the population observation side. So that would be my first guess. I think we can, again, look at this as we see how the outlines are progressing. But I think there's a big topic, an important one.

Let's see. Dorothy or Mark, who wants to be in the lead on this?

DR. CLANTON: This is Mark.

DR. SAMET: Yes.

DR. CLANTON: Let's see. I actually submitted a note saying I'm happy to lead number 7. So if Dorothy's interested, I'll take her lead on this one and support the writing group.

DR. HATSUKAMI: Sure. I can take the lead.

DR. SAMET: Okay. Thank you. Let's see. So that was 5.

All right. Then we're at 6. And probably -- let's see. Probably I should join in this one, on the epi side.

Let's see, Mark. You said you would take

the lead on 7.

DR. CLANTON: Yes. That's correct.

DR. SAMET: Yes. And then, Neal, we already have you in the lead on 3, correct?

DR. BENOWITZ: Yes.

DR. SAMET: So maybe you and I, between us, should just lead this one, with sort of just a split in the epi versus the non-epi, the other lines of observations.

DR. BENOWITZ: That's right. I assume biomarkers are part of this as well?

DR. SAMET: I think biomarkers would be part of this, yes.

DR. BENOWITZ: Yes. Sure. I'd be happy to co-lead it with you.

DR. SAMET: Okay. Now, then we're at 7. And I think this is obviously a critical chapter. I mean, I think the extent to which we have any additional information available, modeling results and so on, is unclear. So this might be qualitative in its approach; it might be quantitative. And I think we'll have to see where

this is.

Let's see. Comments. Karen?

MS. DELEEUW: Yes. I would like to join number 7 also.

DR. SAMET: And Mark had volunteered to lead this. Mark, comment?

DR. CLANTON: Yes. I was going to say that number 7 is going to be so broad that we'll probably welcome formal inputs from everyone on the writing group. I suspect that we'll end up drawing conclusions from other pieces of the report. But number 7 is a pretty broad area.

DR. SAMET: Yes. And I think, again, this is one where the format, how it's going to be captured, will be a challenge for us.

Let's see. So there's a comment that we -- let me go back. Number 4, we're leaderless. That is the smoking -- ah, okay.

So Patricia, do you want to be in the lead on number 4?

DR. HENDERSON: Sure.

DR. SAMET: Thanks. And, let's see, do

we have new hands up?

Greg, you have your hand up. Do you have another comment?

DR. CONNOLLY: Yes, Jon. Go back to 7. We've been talking about establishing a chapter for marketing and special populations. One, is it an extension of a larger report? Do we try to include that in that larger piece?

Then, number two, 7, in a sense, overlaps with committee conclusions. When you say public health impact, you're answering what the statute has asked. And that's just sort of an editorial point.

So there's two things I've made. One is do we include high-risk groups in marketing under 7, Mark, just to add -- just to make sure you're not going to work for three or four months on this report. Then, number two, how does that impact on the conclusion under 8?

DR. SAMET: All right. So again, I think, in part, the question of the public health impact and what it looks like obviously feeds

directly into conclusions and recommendations. The question is how we're going to drive it and whether this will be working within the framework to pull together the committee's view of how the availability of menthol cigarettes affects public health, whether that's done qualitatively or quantitatively. I think it's still not yet clear.

I think we can keep the separation. I think we do need to discuss the -- come to closure on the special populations and marketing. And we in a sense have a proposal just from Dorothy to just run through all topics -- and I know she's got her hand up -- or that it be pulled out into a special section.

Dorothy?

DR. HATSUKAMI: Yes. I just wanted to mention that one area that we hadn't talked about, the one that Neal had brought up, which is contraband. And I'm wondering whether that should be part of the public health impact as well.

DR. SAMET: Okay. So why don't we tuck that there for now, put that under --

DR. CONNOLLY: Jon, I don't think contraband is part of the charge.

DR. SAMET: But we could -- so let me try and reframe the title. It could be "Impact," and then there could be sub-consequences. I guess I think that could be done. I think if we want a chapter that's labeled "Public Health Impact," we can keep it separately. I'm not sure.

So why don't we do this? Let's put this on the list of things we want to make sure we cover and note that we need to cover contraband.

DR. CONNOLLY: Jon, this is Greg. I think we're a public health committee. And I think by deviating into areas of economics, that's something that would be best done with other entities within FDA, and we'd get on shaky ground. That's just my recommendation, that we stick to our science and not to an area that we are not expert in, and we stick to the statute.

DR. SAMET: Okay. We'll have this on the reserve list and decide what we're going to do with this.

Now, number 8, which says committee conclusions, subcommittee -- so our subcommittee, of course, will be offering its report to the full TPSAC for review, comment, acceptance, and so on. I think for now, we should probably not make any assignments we're not going to be -- at this point, we've got to lay the ground work, and I think obviously it's probably something we'll work on together, so that we leave this open.

Let me ask, now, if we go back, we still have the special populations and marketing, I think, have some discussion. Before we do that, let me see. I've got -- I just want to check.

Let's see. Dan, do you have a comment, a new one?

DR. HECK: Yes, Mr. Chairman. We saw earlier in the slides that the CTP has requested that the industry representatives collaborate on a document that would serve as the industry's perspective.

How will that stakeholder input be received or work into this process? Presuming

that that industry document is structured in parallel to this one, how will that stakeholder input be considered in the formation of the advisory report?

DR. SAMET: Now, let me ask first -- and again, I think we're all feeling our way through a new process. I appreciate the point that there will be materials that the full TPSAC members will need to evaluate that will be offered in your perspective.

Karen and Corinne, can you help me out here?

DR. HUSTEN: I think the easiest thing would be to put up a slide that's industry perspective and find out which of the industry representatives would like to be on that workgroup.

DR. HECK: And just procedurally, will you, Mr. Chairman, be involved with this element of the report preparation here, or will this be something that will be totally handled by the nonvoting representatives?

DR. SAMET: Yes. So I guess there are two issues. One will be what is the process by which the industry representatives prepare the report. I think second is what is the process by which that input would be considered.

So Karen, Corinne, any comments? It seems to be, in part, a matter of timing.

DR. HUSTEN: Well, our anticipation was that this would be written concurrently and as the discussion is happening in the subcommittee and in the committee, but as information would be coming back and incorporated as industry desired to do the section.

So we had envisioned it that the industry perspective would be totally up to the industry as far as if they wanted anybody else on it other than the industry representatives, that it was their section and they could have control of that section.

DR. HECK: But as I understand it, the subcommittee working group process will be closed. So will there be an opportunity for participation

in these key chapter developments, is what I'm wondering. These are not going to be public meetings.

DR. HUSTEN: Yes. And just let me remind everybody, though, that although the workgroups will be conducted in closed session, that those reports will be coming back to the subcommittee in an open meeting. And those materials will be available for everybody on the subcommittee to review and comment on. Similarly, that the entire subcommittee report will be taken to the TPSAC and be available for review and discussion by the entire committee, including industry representatives at that point. So there are many opportunities for the industry to see drafts and to have input into the sections and then the full subcommittee report.

DR. HECK: I think that would be important in terms of our obligation to include stakeholder input as a formal requirement.

DR. HUSTEN: Yes. And obviously, these reports, the sections will be coming back in an

open meeting, an the full report will be coming back to the TPSAC in an open meeting. So there'll be opportunity for public comment as well as industry input.

DR. SAMET: Again, I think, Dan, appreciate the comments. And I guess we all have to recognize that we're just feeling our way through. It's a brand new process for all of us.

Let's go back to the marketing issue. Let's see. Just before we do that, I guess, Arnold, do you have your hand up?

MR. HAMM: Yes, I do, Mr. Chairman. Could we come back to slide number 7? Yes, public health impact on menthol. And this is kind of touching on something that Dr. Connolly spoke to about was it appropriate to mention the black market or contraband.

In the House committee report that accompanied the legislation, it does talk about questions of public health that might be posed by a ban. And it talks about, for example, the healthcare system might not be capable of handling

the sudden increase in demand for cessation assistance, and the case of a more broadly-used product, leaving millions of smokers without medical support.

I'm just wondering, in number 7, would it be appropriate to address that particular issue, because it is a public health issue.

DR. SAMET: Well, one thing I will certainly say, I don't feel current enough on the issue to know how it fits within our charge. This is something that the subcommittee itself can make this -- the writing subgroup can make the determination as to where it fits and give us some guidance on this. We've heard one opinion already from Greg on this topic.

So what I would suggest is that this is a matter that does not need to be necessarily resolved today, but one that the subcommittee can take a -- for number 7, take a look at.

DR. HUSTEN: Jonathan?

MR. HAMM: So you're suggesting putting --

DR. SAMET: I think I hear a voice in the background.

DR. HUSTEN: Yes. Jonathan, this is Corinne. I just wanted to remind the group that the statute does say that the committee shall address considerations in subsection (a)(3)(B)(i) and (v), and that those include the effect on initiation and cessation, but also includes achievability and the potential effect in terms of contraband.

So I think the committee does need to decide how they will incorporate those issues into the report.

DR. SAMET: Thank you. And again, I think -- so we'll leave that as an issue of where it goes in the report. I'm not sure right now, but it's noted.

Let's see. John Lauterbach, do you have a comment?

DR. LAUTERBACH: Yes, Dr. Samet. I had one comment, that in the meeting materials received today, there were letters submitted to

the TPSAC about concerns of law enforcement on contraband.

Then my second question was to Dr. Husten about in terms of why we consider -- I hate this term "industry report" because I'm here for the science first. But how do we express our views, and any terms of where there is not total consensus within the committee, how our different views -- different scientific views going to be expressed in this report?

DR. HUSTEN: Well, again, as with any advisory committee, I think the committee has to grapple with how they make sure that all the perspectives are represented in the report.

DR. SAMET: This will not be the first time that a group with diverse opinions has had to write a report. I think we will work through these issues.

Karen?

MS. DELEEUW: I'm sorry. I don't have my hand up.

DR. SAMET: Oh, okay. You still did

electronically.

Let me make the suggestion that we go back to --

DR. CONNOLLY: Jon, I still have my hand up. Jon? I have my hand up.

DR. SAMET: Yes?

DR. CONNOLLY: I would just make a couple comments. I think under 8, we did include recommendations. We are different than an NIH panel in that we are translating science into policy. And I think recommendations are critical. It's probably the second component of the report, so it's important that we consider recommendations. I think we've got to be careful in terms of the scope, the work, the efforts (unclear) in the report, and just what we can accomplish and what our expertise is.

The other point -- which I know we all disclose, and public presenters disclose, conflicts. I was just curious, when letters are submitted to FDA, do we alert the letter writer to report conflicts? That's a question for Karen.

Well, first take that recommendation.

DR. SAMET: Yes. We discussed that. I think that's because --

DR. CONNOLLY: That's my point on that.

DR. SAMET: Okay. We've got that.

DR. CONNOLLY: And then --

DR. SAMET: I'm not sure I fully understand your --

DR. CONNOLLY: Well, there was a series of letters submitted to the committee. And I did some investigation, and there's some questions about industry support from some of those. And I think do we alert letter writers who go on the record that there are conflict of interest statutes.

DR. SAMET: Well, I think we in the public comment make those remarks about potential financial interests, and whether anyone chooses or not to disclose them, they're still allowed to make a presentation. I would assume that that applies equally to written submissions.

Karen, do you have any comment on that?

[Dr. Husten responds.]

DR. HUSTEN: Yes. That's correct.

DR. SAMET: I think I read the --

DR. HUSTEN: While we're on slide 8 -- this is Corinne -- if I could just make one comment. We at FDA have had -- although the subcommittee contains many of the members of the committee, it does not contain everybody who's on the full TPSAC. And so, it had been our anticipation that it would be the full TPSAC that would develop the recommendations for the report, and that the conclusions of the subcommittee regarding the scientific evidence would obviously help determine those; but that it was really appropriate to get the input of all the TPSAC members on considering the recommendations.

DR. SAMET: Great.

DR. CONNOLLY: Well, let me respond by saying that I respect that very much. But in watching the last committee -- the last meeting and the committee's actions, that many seemed surprised by the subcommittee popping up and

presenting.

I think discussion at the subcommittee level can help flesh out that. Since we, the committee, are constructing this report, I think it could be helpful to the larger committee. Unlike the last committee that reported, there were only two members -- one was recused -- we now have a fairly good representation.

So I think a discussion, an active discussion, of recommendations are important based on the writers so that the larger committee can get a feel for the deep consideration of the science and the application of the science to policy.

DR. SAMET: I want to come back and focus in on the special populations and the marketing issue, which I think is still unresolved.

Let me ask, perhaps, Dorothy, do you want to elaborate on your comment, which I think set out one approach? And that was, let's say, probably a subsection within the different chapters, highlighting information relative to

special populations, as available. I'm not sure where that leaves marketing. Marketing is, in part, a special populations issue.

So comments on how we might organize?

DR. HATSUKAMI: Well, I would think that rather than have the special population -- if we had a topic on special populations, rather than going through each of the topics to see how they're relevant to a special population, it will be a lot more efficient if each of the topics could address the impact of, for example, abuse liability or disease risk. So I think that the cross-cutting would be good.

But on the other hand, as Greg said, I certainly don't have any problems with having a special chapter on special populations, but I wouldn't know what the nature of that would be. And maybe Greg can clarify what he might --

DR. SAMET: Well, yes. Greg, before you talk, if we took Dorothy's approach, then special populations, there would be a summary and synthesis of the evidence on special populations

in chapter 8, and perhaps something coming from chapter 7 as well, oriented towards special populations.

So that would be one approach. Another would be to have a chapter that joins together all the materials. In either case, it needs to be synthesized in some way.

So let's see. Greg and then Mark.

DR. CONNOLLY: Jon, I would agree with your latter recommendation that we have like a summary chapter on special populations, given the nature of how this recommendation came about in Congress and given the burden that this places on special populations. For the committee not to do that, I think it could weaken the impact. So I would recommend that we do both, and I don't think it would add an awful lot of burden.

Then, also, I just want to make sure under 8 that either we vote -- that we have to vote on the committee's conclusions and recommendations, or we all agree to the committee's conclusions and recommendations;

because, again, that's what's specifically stated in the statute, part 2, and not walk away without an agreement.

DR. SAMET: Yes. I think that's a process that we'll come to down the line.

DR. CONNOLLY: Okay. And then the final thing, Jon, as we come down the line, are we going to have external individuals that we ask FDA to appoint to become special employees and work on this project? Are we going to have a budget to hire individuals or does the timeline constrain that?

DR. SAMET: So Karen, do you want to comment on that, or Corinne, just comment?

DR. TEMPLETON-SOMERS: The budget won't be necessary. If there's someone with expertise that's not represented and you feel they need to be included, you need to let the DFO know. We'll see about if they can become special government employees, if they are not already. And then after they're screened for conflict of interest, they can be utilized. Budget's not the issue.

DR. CONNOLLY: I think tied with that, Karen, is that as a member of a writing group of a chapter, that if we introduce evidence -- it sounds like Jon will establish a framework for evidence. But what role would CTP play in saying, well, that is or that isn't evidence, or will allow it or not allow it?

DR. SAMET: Well, no. Actually, we are writing the report, not CTP. So your hypothesized role, it doesn't exist.

DR. CONNOLLY: Okay.

DR. SAMET: Okay. Let's see. Somebody else.

Mark?

DR. CLANTON: I just wanted to say, on the issue of special populations, I think the best way and the most elegant way of representing the impact on a special population of menthol is probably to do it in a cross-cutting way, and to somehow represent the appropriate commentary in each section.

But having been through part of a

process, or government processes (unclear), that attempts to do that, I just want to say it's actually technically challenging to make sure that happens. In other words, some individual in each group then has to be accountable and responsible for making sure that that happens within a particular group. So I'm in favor of it. I think it's the best way to represent it. But I've found it technically challenging to make sure that it happens.

So we'll sort that out, I guess, in a committee meeting. But either in a section of its own or having it appropriately represented in the public health impact section where all of the comments come together is one easier way of doing it. But if we can overcome the technical hurdles of having it represented in each area, that is the most elegant way of going back to it.

DR. SAMET: So one suggestion, again, would be that if we follow what I'll call the decentralized approach, that each group, as it develops its outline, needs to make certain that

special populations are covered. And then a way to continue with what I think Mark's proposing, perhaps as in chapter 7, for sure, there'd be a specific discussion of special populations. Then within chapter 8, I think we can anticipate that there will be conclusions and recommendations related to special populations, so they would be carrying through.

I think if we find efficiencies in that approach, once we've done it, we could reorganize the material. I think we would have it, and pull it into a special chapter. But I think it was highlighted in 7 -- if special populations are highlighted in 7 and 8, that may work. And then as each writing group develops their outline, they could make certain that they include a designation for the evidence on special populations for each topic.

Can we start with that for now?

DR. CLANTON: This is Mark. I think that's a rational way to approach it.

DR. SAMET: So we'll do that. We'll take

what I'll call the Dorothy approach, and then we'll just see. And if we need to regroup, we can do it. We'll have the material pulled. So I think it's a highlighting in 7 and 8 that is what's particularly important.

That still leaves us with marketing. So what about marketing? And I guess two comments here. One is whether we handle it. And then the other is, is this an example where we do need some help from some additional people who might be brought in to work with us on the marketing issues.

Dorothy, let me ask you to lead off on this.

DR. HATSUKAMI: Okay. Actually, marketing could be potentially subsumed under the consequences of menthol smoking for initiation and cessation because I would suspect marketing is part of initiation.

But related to marketing, I think one area that needs to be addressed would be consumer perception as well, perception of harm or health

benefits or whatever. So I guess that's two issues. One is that we need to consider consumer perception; and secondly, I'm just wondering if marketing should be part of number 5.

DR. SAMET: Okay. Greg?

DR. CONNOLLY: I'd agree with Dorothy. I think we can include it. But at the same time, it does deserve a good discussion. We saw it presented before the committee, the issue of price discounting. It was not (unclear) on differential marketing, which again mixes this issue of equality with science, so trying to build a science responsive to the public health. But I think it could be assumed, but at the same time, we should not downplay the importance of marketing.

I think perception begins to fall in item number 3, perceptions and the use of drugs, if that's what I'm hearing you say. I see that related to abuse liability, particularly in light of the Controlled Substances Act. I understand that in that Act, it looks at constituents that

would affect abuse liability.

I agree with Dorothy, but I just think we've got to -- maybe you have to bring in an outside expert on the marketing piece to strengthen where we need to be.

DR. SAMET: Well, that was my other question. And then, perhaps, if we are looking to follow, Dorothy, your lead on where we put some of the marketing material, I think one immediate question is we don't have Melanie involved in this subcommittee. So the question of whether we bring in additional expertise on marketing I think is something we should think about quickly because that's a process that should be initiated right away.

Dorothy, would you like to comment?

DR. HATSUKAMI: Yes. I will agree that we should bring someone in for marketing because I certainly don't have that expertise. I also would agree with Greg, too, that perhaps consumer perception should be part of number 3, because I think that abuse liability and consumer perception

does go hand in hand. So I do agree with Greg.

DR. SAMET: So we've got marketing put under number 5 for now. Consumer perception under number 3. We have agreed that we want to bring in additional marketing expertise.

Let's see. What other things? So I think we've gone through the outline and we have names by it. Just in terms of tasks and responsibilities, I think those of us involved in number 1 and 2, I think, probably need to get our act together real quick. And I think we should try and put some deadlines by this.

But I would think those working on number 1 and 2, I can put together sort of an expanded outline and approach for discussion, and we probably should get a call scheduled within the next few weeks. I think, again, I'll have to sit back and think about a schedule. We might do a little of that here. But I'd still like to backtrack with FDA on our report, bringing it to the full TPSAC, and the timing on this March date.

Since I'm going to actually have the

opportunity to talk with Corinne and Karen tomorrow, maybe this is something we could go through and then send out a detailed schedule for the committee.

But I think those of us in groups 1 and 2 have some of the most immediate responsibility. I mean, I would see the process as development of quite detailed outlines of what points need to be covered, at least, in each of these chapters, what evidence will need to be gathered? We have to think about how to approach it, and look at the schedule.

I agree. We're heading for October. We roughly have four working months before February. And again, I think -- don't panic because we can only do what time is allowed. And then we have the opportunity in recommendations to suggest what else might need to be done, where evidence might need to be gathered, and so that uncertainties continue to be narrowed.

Let's see. Neal?

DR. BENOWITZ: I just have a question

about the detail. This is like a surgeon general's report. How much detail do you want to include?

DR. SAMET: Yes. So I think your analogy is good. Obviously, we don't have time to produce the Surgeon General's report. And I think we have to balance off the need to have a clear and thoughtful summary of the most relevant evidence against the time frame. For those of you who know the Surgeon General's reports, they're years in the making, and we don't have time for that kind of process.

So I see this as something much briefer, Neal, than an Institute of Medicine report, something more in that spirit, where it's clear how we've gathered evidence, identified key studies, but we perhaps are not going to have hundreds of pages of exhaustive tables summarizing all evidence available, which is the Surgeon General's report style. It's just not feasible.

Dorothy, do you still have your hand up?

DR. HATSUKAMI: Yes. I think that one

issue that we haven't discussed is the contrabanding issue, whether to include that in the report. And it is true, what Dr. Husten has mentioned, that it is part of TPSAC's charge to address that.

DR. SAMET: Right. So we actually did, I think, come to the point where we recognized that we would need to deal with this. I think that perhaps, at least, my suggestion would be that the chapter 7 group give consideration to this; that we as a committee remind ourselves of responsibility towards contraband, think about where it goes.

But I would put this as at least a sub-responsibility for now for the number -- those dealing with number 7. And perhaps it will go somewhere else, but let's put it under their mandate.

Greg?

DR. CONNOLLY: Yes. I wasn't knowledgeable on sections of the report. And I think Corinne is right; it has to be considered.

In this case, as with the case of marketing, there are experts that deal with issues of contraband that we can consider consulting with.

DR. SAMET: Yes, it's a good point. So that's something actually, Mark, your group probably should quickly think about whether you need a special government employee to help with contraband.

Okay. Other comments? I actually have a request from Corinne and Karen for another break so they can just put together a summary of what we have gone one. So I have briefly summarized what we have done and I think some of the things that we need to get into order, like our schedule and a little bit more on the lining up the working groups to get their outlines written and shared. We can probably come back to that after the summary from Corinne and Karen.

So let me ask, if we took a break now, how long do you need?

DR. HUSTEN: I think 10, probably, is enough. We just want to make sure that each of the

slides has captured what you've been saying, and then have you all go back through it and make sure that we have everything on the correct slide, and the right people on the slide, and all of that. So we just want to take a few minutes to organize it a little bit.

DR. SAMET: All right. So let's see. We're at 9:00 here, so noon. So how about -- why don't we say quarter after the hour. Okay?

DR. BENOWITZ: Jon?

DR. SAMET: Yes?

DR. BENOWITZ: I've got to catch a flight. I've got to leave in about 15 minutes. So I'll have to sign off now.

DR. SAMET: Thank you very much, Neal, for participating. You'll hear from us, no doubt.

Okay. Thanks, and in 15 minutes we'll reconvene, quarter after.

(Whereupon, a brief recess was taken.)

DR. SAMET: I'm ready. So if I understand what you've done, you've gone back through, and you want to go through the slides

again in a sort of more refined designation of assignments and so on.

DR. HUSTEN: Yes. We tried to just make sure we had captured all the topics and moved them to the right place and everything. So if everyone can just take a look at it again and make sure I did it correctly.

DR. SAMET: Okay Sure. Sure. So let's go through. So 1 and 2 -- okay.

DR. HUSTEN: Give us just one second.

DR. SAMET: Okay.

DR. HUSTEN: We just have to make sure that what's pulled up here is what you're seeing as well. Just give us one second.

DR. SAMET: Okay. Sure.

[Pause.]

DR. HUSTEN: We have it now.

DR. SAMET: So shall we go back number 1, then, which was combining with number 2, Greg, Dorothy, Mark, and myself, fast-tracked because it's fundamental. And number 2 is our evidence evaluation approach, gathering evaluation.

So 3 is now physiological effects that includes relevant chemistry, abuse liability, chemosensory and pharmacological effects, and possibly consumer protection, to be determined if appropriate here. Neal in the lead, Greg, and Dorothy. And this would be one, if we are adding marketing and consumer protection experts, who might come in here, too.

Number 4 is more of the descriptive chapter, Patricia taking the lead, with Karen and Greg helping out.

Five, okay, so this one, consequence of menthol cigarettes, or mentholated cigarettes, for initiation and cessation, possibly with the addition of additional expertise, cover marketing here. I guess probably not possibly; if we know for sure, Dorothy, I think we want additional expertise here, don't we?

DR. HATSUKAMI: Correct.

DR. SAMET: Yes. So we should have a conversation about how to do that. So additional expertise needed, no question mark.

Then 6, this is the one with Neal and myself in the lead, Mark. And this would include tox, biomarkers, and epidemiology.

Seven, public health impact. Perhaps one of the points at which special populations would be summarized. This group, at least, would have the charge of deciding what we should do about contraband and where we would put it, I think probably with a rapid determination on what additional expertise do we need for that topic. Mark in the lead here, with Patricia and Karen.

Then 8 is the -- not for now, and no specific assignments at this point. And some of the holding issues here, in a sense, is making sure we like the way we're handling special populations in this kind of matrix approach across chapters. And contraband we need to find a home for.

I think those were probably the issues. Needed expertise on marketing, and we know we need expertise on contraband as well, so we should probably go ahead and identify -- put it in there.

So this is helpful updating. And we also have the pending issue of the extent to which the industry representatives can participate, which is something that the FDA will determine. And the industry perspective contribution to be developed. And again, that's new territory here to cover.

Let me ask the industry representatives. Have you had any discussions about how to approach this yet?

DR. LAUTERBACH: Dr. Samet, we're going to try and meet on this within the week or so and see if we can work this out.

DR. SAMET: Okay. Thank you, John.

Additional comments from the subcommittee members?

[No response.]

DR. SAMET: Then to come will be guidance on schedule and so on for getting this done, and I think maybe some more specifics about how we can work with the science writers.

Greg?

DR. CONNOLLY: Jon, on 3, if we could

just keep marketing out of 3 and let it stand as an assessment of abuse liability. I think once you put marketing in 3, then you're going to may run a risk of having a lack of focus. Okay?

DR. SAMET: Okay. Other comments?

[No response.]

DR. SAMET: So the next order of business, I think, will be to get a schedule on what to do. But, obviously, the writing groups will need to meet and develop their own more detailed outlines and assignments.

Let me ask if there are other general questions.

[No response.]

DR. SAMET: And I think further details on things -- for example, size and format -- I think we can -- Corinne or Karen, we can provide that in a sort of more detailed follow-up note. Is that fair?

DR. TEMPLETON-SOMERS: Sure. That will work.

DR. SAMET: Yes. That will work.

Remember, the Surgeon General's reports are incredibly valuable resources for being encyclopedic, but it takes a long time to write an encyclopedia. So that's not our goal.

Other things that we want to cover today while we're here together?

[No response.]

DR. SAMET: Then, let's see. Do we have anything else? Corinne? Karen? Do we have closing remarks? Is Glen Jones going to make closing remarks for us?

DR. JONES: Yes, Jon. Can you hear me?

DR. SAMET: Yes, I can. Please go ahead.

Closing Remarks

DR. JONES: Really, just to wrap up, I appreciate everyone getting together this morning for this important kickoff of the report. I appreciate everyone's time today, and more importantly, the amount of time that each of you have agreed to put into this process in the coming months.

We realize you have other jobs and other

things to do. And this is a huge task with, as has been mentioned several times today, an aggressive timeline. But thank you, and I hope everyone has a good day.

DR. SAMET: Okay. Good. And let me thank you all for your participation. And remember, it's only about a week and a half or so, two weeks, till we are together.

So thank you very much. And then, Corinne and Karen, if you could perhaps give me a call back just to talk about how we might get together tomorrow when I'm in D.C.

DR. TEMPLETON-SOMERS: Sure.

Adjournment

DR. SAMET: All right. Thank you, everybody. Lots of hard work ahead, and hopefully we'll be, in March, looking at a report that will be valuable and make a difference. Thanks. Bye.

(Whereupon, at 12:26 p.m., the meeting was adjourned.)